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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/719,359 | 11/21/2003 | Diane Harris Boschelli | AM101163 | 4087 |
| 25291 | 7590 | 06/24/2004 | EXAMINER HUANG, EVELYN MEI | |
| WYETH PATENT LAW GROUP FIVE GIRALDA FARMS MADISON, NJ 07940 | | | ART UNIT 1625 | PAPER NUMBER |

DATE MAILED: 06/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/719,359 | Applicant(s) BOSCHELLI ET AL. | |
| | Examiner Evelyn Huang | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
 4a) Of the above claim(s) 19-37,45-52,55 and 56 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41 and 43 is/are allowed.
- 6) ☒ Claim(s) 1-3,6-10,12,15-17,38-40,42,44,53 and 54 is/are rejected.
- 7) ☒ Claim(s) 4,5 and 18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-18, 38-44, 53, 54, drawn to a thienopyridine compound, classified in class 546, subclass 114, and the composition thereof.
 - II. Claims 20, 22, 56, drawn to an intermediate compound.
 - III. Claims 19, 21, 55, drawn to different processes for making the compound.
 - IV. Claims 23-37, 45-52, drawn to different processes for using the compound.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product is deemed to be useful as an intermediate in the making of other compounds and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP §

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806.05(f)). In the instant case, the thienopyridine compound can be synthesized by the method of Khan (PTO-1449).

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different processes, such as in the treatment of cancer, stroke, neuropathic pain, arthritis etc.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for the other groups, the search is not co-extensive and is burdensome, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Ms. Goudie on 6-10-2004 a provisional election was made with traverse to prosecute the invention of group I, claims 1-18, 38-44, 53, 54. Affirmation of this election must be made by applicant in replying to this Office action. Claims of Group II-IV inventions are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise**

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include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 16, 17, 42, 44, 53, 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 14, 16, 42, 44, 54, 'comprising' in 'a compound comprising' is open-ended and is therefore indefinite. Amending the claims to the proper Markush language is recommended.
- b. Claim 17 is an independent claim, but the definitions are improperly referenced back to claim 1. If this is intended to be an independent claim, the definitions should be recited in the claim.
- c. Claim 53, it is unclear whether this is a compound claim or a composition claim since the compound and the pharmaceutical acceptable carrier are recited in the claim. Clarification is required.

Duplicate Claims

6. Claim 44 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 42. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 103

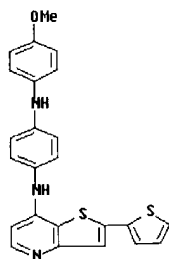
7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-10, 12, 15, 38-40, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Munchhof (6492383) in view of Luzzio (US 2002/00004511).

Munchhof generically discloses a thienopyridine compound useful as anticancer agent (columns 2-3). A specific example is described (column 67, lines 5-6) having the following structure.

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Munchhof's example compound has a hydrogen whereas the instant has a cyano on the thienopyridine.

Luzzio, in a similar thienopyridine anticancer compound, teaches that hydrogen and cyano are optional choices (page 1, [0010], definition of X).

At the time of the invention, one of ordinary skill in the art would be motivated to replace the hydrogen of Munchhof's compound with the alternative cyano as taught by Luzzio to arrive at the instant invention with the reasonable expectation of obtaining an additional compound useful for treating cancer.

Allowable Subject Matter

8. Claims 4-5, 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 41, 43 are allowed.

In addition to having a cyano instead of the prior art hydrogen, the phenyl of R1 in the instant claims 4-5, 13 is optionally substituted with Cl, R4 or OR4, thereby setting a further demarcation from the closest prior art example compound (column 67, lines 5-6), wherein the phenyl is substituted with methoxyphenylamino. Motivation to modify the prior art compound via multiple changes to arrive at the instant invention is lacking.

In addition to having a cyano instead of the prior art hydrogen, the sulfur of the thienopyridine compound of instant formulae 1c-1f is further oxidized. Motivation to modify the prior art compound via multiple changes to arrive at the instant invention is lacking.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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